K090078

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: K090078

MAY - 8 2009

Contact Person: Jason Malecka
President
IOP, Inc.
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Date Prepared: December 29, 2008

Device Name and Classification

Proprietary Name:	KeraSys Bioengineered Lamellar Patch Graft
Common Name:	Ophthalmic Implant Biologic
Regulation Name:	Ophthalmic Conformer
Regulatory Class:	Class II (Exempt from Premarket notification procedures)
Product Code:	NXM
Proposed Classification No.:	886.3130

Device Description

The KeraSys Bioengineered Lamellar Patch Graft is constructed from four layers of laminated porcine small intestinal submucosa (SIS). The dehydrated device is supplied sterile sealed in a double peel pouch system. Unit size is 1x1.5cm

Indications for Use

The KeraSys Bioengineered Lamellar Patch Graft is intended for implantation to reinforce sclera and aid the physical reconstruction of the ocular surface.

Summary of Testing

The Surgisis family of devices has undergone extensive biocompatibility testing, viral inactivation testing and mechanical testing. Outcomes demonstrate safety and efficacy for soft tissue reconstruction.

Substantial Equivalence Claim

KeraSys Bioengineered Lamellar Patch Graft is similar with respect to intended use, materials and technical characteristics to predicate devices.

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Predicate Device Equivalence

Company	Innovative Ophthalmic Products Inc.	Cook Biotech Inc.	Innovative Ophthalmic Products, Inc.
Product Name(s)	SURGISIS Ocular Graft tarSys Bioengineered Eyelid prosthesis	SIS Facial Implant	keraSys Bioengineered Patch Graft 1x1.5cm
510(k)	K053622	K050246	Applied for 510(k) K090078 Pending
Product Specifications			
Material	Processed porcine submucosa	Processed porcine submucosa	Processed porcine submucosa
Indications for Use	The SURGISIS Ocular Graft is intended for implantation to reinforce and aid reconstruction of eyelid and is labeled for single use	Reinforcement of tissue where weakness exists in patients requiring soft tissue repair or reinforcement in face, head and plastic and reconstructive surgery	The KeraSys Bioengineered Lamellar Patch Graft is intended for implantation to reinforce sclera and aid the reconstruction of the ocular surface.
Supplied	Sterile	Sterile	Sterile
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Recommended Usage	Single Use	Single Use	Single Use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2009

IOP, Inc.
c/o Mr. Jason Malecka, President
3184-B-Airway Ave.
Costa Mesa, CA 92626

Re: K090078
Trade/Device Name: keraSys Bioengineered Lamellar Patch Graft
Regulation Number: 21 CFR 886.3130
Regulation Name: Ophthalmic Conformer
Regulatory Class: Class II
Product Code: NXM
Dated: April 15, 2009
Received: April 17, 2009

Dear Mr. Malecka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090078

Device Name: KeraSys Bioengineered Lamellar Patch Graft

Indications For Use:

The KaraSys Bioengineered Lamellar Patch Graft is intended for implantation to reinforce sclera and aid the physical reconstruction of the ocular surface. KaraSys is labeled for single use.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K090078